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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,008	08/02/2001	Daniel G. Schmiel	6683.47US11	5027

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EXAMINER

LEWIS, RALPH A

ART UNIT PAPER NUMBER

3732

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/921,008

Applicant(s)

SCHMIEL ET AL.

Examiner

Ralph A. Lewis

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 and 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 28-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **Acknowledgement of Election**

Applicant's election of Group II, claims 18, 19 and 28-66 without traverse in paper number 8 is acknowledged.

### **Obvious-type Double Patenting Rejection**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18, 19, 50, 51, 55, 56, 57, 58 and 62 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,626,905 B1 in view of Mehdizadeh (5,803,904).

Patented claim 8 of applicant's earlier application sets forth the "forming an implant bore," the inserting an intervertebral implant" and the "mounting external stabilization" limitations, but fails to set forth how the vertebral bodies are distracted. Mehdizadeh, however, teaches that it was known in the prior art at the time of applicant's invention to use a retractor tube for distracting the vertebral bodies and

guiding instruments wherein the retractor tube includes a paddle and angled distal edge. To have used the prior art Mehdizadeh intervertebral retractor in the patented '905 method would have been obvious to one of ordinary skill in the art as an obvious selection of a proper known tool for the earlier patented procedure.

In regard to the kit claims, merely providing the tools used in the above claim 8/ Mehdizadeh combination together in a kit so that they are readily available to the surgeon would have been obvious to one of ordinary skill in the art.

Claims 18, 19 and 37-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,626,905 B1 in view of Mehdizadeh (US 6,030,390).

Patented claim 8 of applicant's earlier application sets forth the "forming an implant bore," the inserting an intervertebral implant" and the "mounting external stabilization" limitations, but fails to set forth how the vertebral bodies are distracted. Mehdizadeh, however, teaches that it was known in the prior art at the time of applicant's invention to use a retractor tube for distracting the vertebral bodies and guiding instruments wherein the retractor tube includes a paddle and angled distal edge. Mehdizadeh further discloses the use of a wedge shaped plug distractor 27 for separating the vertebral bodies. To have used the prior art Mehdizadeh intervertebral retractor in the patented '905 method would have been obvious to one of ordinary skill in the art as an obvious selection of a proper known tool for the earlier patented procedure.

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In regard to the kit claims 37-66, merely providing the tools used in the above claim 8/ Mehdizadeh combination together in a kit so that they are readily available to the surgeon would have been obvious to one of ordinary skill in the art.

### **Rejections based on Prior Art**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28, 29, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehdizadeh (US 5,803,904).

Note tube 26, angled distal edge 29 and paddle 27.

Claims 28, 29, 31, 32, 37, 39 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehdizadeh (US 6,030,390).

Note tube 22 with angled distal end and paddle 23. In regard to claim 37, note distractor 27.

Claims 28-32 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Bryan (US 5,306,275).

In Figure 14, note tube 132, angled distal end 134 and the two paddles formed by openings 133 and 134.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehdizadeh (US 5,803,904).

The selection of the particularly claimed angle and the use of a conventional stop would have been obvious to one of ordinary skill in the art in constructing the Mehdizadeh device as a matter of routine.

Claims 33, 34 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehdizadeh (US 5,803,904).

The selection of the particularly claimed angle and the use of a conventional stop would have been obvious to one of ordinary skill in the art in constructing the Mehdizadeh device as a matter of routine.

Claims 33, 34, 36, 50, 51, 55-58, 62, 63 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan (US 5,306,275).

The selection of the particularly claimed angle and the use of a conventional stop would have been obvious to one of ordinary skill in the art in constructing the Bryan device as a matter of routine.

In regard to the kit claims, Bryan additionally discloses pedicle screws and rods (see Figure 12), merely providing the tools together in a kit so that they are readily available to the surgeon would have been obvious to one of ordinary skill in the art.

Claims 42-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehdizadeh (US 5,803,904) in view of Bryan (US 5,306,275).

Bryan teaches the use of conventional pedicle screws and rods (Figure 12) used in conjunction with a tubular retractor/guide instrument 132 (Figure 14). Merely substituting the Mehdizadeh retractor/guide instrument system for the Bryan retractor/guide instrument would have been obvious to one of ordinary skill in the art as would collecting the instruments together in a kit so that they would be readily available to a surgeon.


**Prior Art**

Applicant's information disclosure statements April 01, 2002 and May 27, 2003 have been considered and an initialed copy enclosed herewith.

Cauthen (US 6,520,967) is made of record.

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(703) 308-0770**. Fax (703) 872-9302. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Kevin Shaver, can be reached at (703) 308-2582.

R.Lewis  
November 3, 2003

  
Ralph A. Lewis  
Primary Examiner  
AU3732